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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,888

04/14/2004

Julia T. Lathrop

2308/680

7107

26774

7590

09/30/2008

NIXON PEABODY LLP - PATENT GROUP  
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EXAMINER

COUNTS, GARY W

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/823,888	<b>Applicant(s)</b> LATHROP ET AL.	
	<b>Examiner</b> GARY W. COUNTS	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 5-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/15/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 26, 2008 has been entered. Currently claims 1, 2, 5-18 are pending and under examination.

### **Rejections withdrawn**

In light of the Declaration of Julia T. Lathrop under 37 C.F.R. 1.132 filed on 12/14/07 and the Petition to correct inventorship under 37 C.F.R. 1.48(b) submitted 05/21/08, and applicants arguments that Hammonds et al 2004/0229280 is not available as prior art, the 102 and 103 rejections based on the primary reference of Hammond et al. US 2004/0229280 are hereby, withdrawn.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 2, and 5-18 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Predetermined or known locations of the ligands on the first support and determining positions of the protein isoform(s) on the

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second support and a step of aligning the first support and the second supports to provide for the identification of the protein isoform critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Page 3, line 28 – pag3 4, line 7 discloses that a ligand library is immobilized on a first support, where each species of the ligand is placed at a unique position within the array. A protein isoform is thereby captured at a unique position in the array based on its interaction with a specific test ligand. Ligand isoform complexes are detected following immobilization of the complexes on the first support. The isoforms are then transferred to a second support and immobilized thereupon such that they are present in positions that correspond to the positions of the immobilization on the first support. Page 4, lines 26-32 of the specification discloses that by aligning the first and second supports and analyzing or comparing the detection results, the ligands to which the various subsets of isoforms were initially bound may be detected, identified and isolated. That is, once the unique position of the protein is identified on the second support, its former position on the first support (where it is captured by the ligand) can be determined, leading to the identification and isolation of the ligand responsible for its original capture. The instantly recited claims read on having a positive signal in both the first and second supports and does not provide for distinguishing or identifying ligands which are specific for the protein isoforms. For example, the claim reads on having multiple ligands and multiple protein isoforms which would form multiple complexes and only provides for detecting a signal from the complexes on the first support and then transferring the

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protein isoform to a second solid support and contacting the protein isoforms with a marker to provide a second signal. Therefore, even if both supports are providing a signal, the claim does not provide where the signal is on the support and one of ordinary skill cannot discern how the ligand is identified or differentiate what ligand is bound to what protein isoform. Therefore one could not positively identify the ligand or ligands having binding specificity for the one or more protein isoforms. It appears that the only embodiment which allows for identification of the ligand having specificity for the one or more protein isoforms requires the determination of the location of the protein isoform on the second support and aligning the second support with the first support to compare the protein isoform on the second support to the known locations of the ligands on the first support in order to provide for the identification of the one or more ligands having binding specificity for the one or more protein isoforms.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 2, 5-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: having the ligands in known locations on the first support and determining the location of the protein isoform on the second support and aligning the first support to the second support to compare

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the signals of the complexes to identify the one or more ligands having binding specificity for the one or more protein isoforms. The specification on Page 3, line 28 – pag3 4, line 7 discloses that a ligand library is immobilized on a first support, where each species of the ligand is placed at a unique position within the array. A protein isoform is thereby captured at a unique position in the array based on its interaction with a specific test ligand. Ligand isoform complexes are detected following immobilization of the complexes on the first support. The isoforms are then transferred to a second support and immobilized thereupon such that they are present in positions that correspond to the positions of the immobilization on the first support. Page 4, lines 26-32 of the specification discloses that by aligning the first and second supports and analyzing or comparing the detection results, the ligands to which the various subsets of isoforms were initially bound may be detected, identified and isolated. That is, once the unique position of the protein is identified on the second support, its former position on the first support (where it is captured by the ligand) can be determined, leading to the identification and isolation of the ligand responsible for its original capture. Therefore, it appears that it is essential that the ligands are in known locations on the first support and determining the location of the protein isoform on the second support and aligning the first support to the second support to compare the signals of the complexes to identify the one or more ligands having binding specificity for the one or more protein isoforms.

Claim 1 is vague and indefinite because it is unclear how one can identify a ligand having binding specificity for the one or more protein isoforms as currently recited. It is

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unclear how the presence or absence of the first signal and the presence or absence of the second signal identifies the ligand. For example, the claim reads on having multiple ligands and multiple protein isoforms which would form multiple complexes and only provides for detecting a signal from the complexes on the first support and then transferring the protein isoform to a second solid support and contacting the protein isoforms with a marker to provide a second signal. Therefore, even if both supports are providing a signal, the claim does not provide where the signal is on the support and one of ordinary skill cannot discern how the ligand is identified or differentiate what ligand is bound to what protein isoform. Please clarify how to identify the ligand.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/  
Examiner, Art Unit 1641

/Long V Le/  
Supervisory Patent Examiner, Art Unit 1641